otherwise be allowable under paragraph (h)(1) of this section, if the Director, determines that application of the higher rates is necessary to ensure the availability of an adequate number and mix of qualified health care providers in a network in a specific locality. This authority may only be used to ensure adequate networks in those localities designated by the Director, as requiring TRICAR preferred provider networks, not in localities in which preferred provider networks have been suggested or established but are not determined by the Director to be necessary. Appropriate evidence for determining that higher rates are necessary may include consideration of the number of available primary care and specialist providers in the network locality, availability (including reassignment) of military providers in the location or nearby, the appropriate mix of primary care and specialists needed to satisfy demand and meet appropriate patient access standards (appointment/waiting time, travel distance, etc.), the efforts that have been made to create an adequate network, other cost-effective alternatives, and other relevant factors. The Director, may establish procedures by which exceptions to applicable CMACs are requested and approved or denied under paragraph (h)(1)(iv)(E) of this section. A decision by the Director, to authorize or deny an exception is not subject to the appeal and hearing procedures of § 199.10. When the Director, determines that it is necessary and cost-effective to approve a higher rate or rates in order to ensure the availability of an adequate number of qualified health care providers in a network in a specific locality, the higher rate may not exceed the lesser of the following:

(1) The amount equal to the local fee for service charge for the service in the service area in which the service is provided as determined by the Director, based on one or more of the following payment rates:

(i) Usual, customary, and reasonable;

(ii) The Health Care Financing Administration's Resource Based Relative Value Scale;

(*iii*) Negotiated fee schedules;

(iv) Global fees; or

(v) Sliding scale individual fee allowances.

(2) The amount equal to 115 percent of the otherwise allowable charge under paragraph (h)(1) of the section for the service.

* * * * *

Dated: August 22, 2001. L.M. Bynum, Alternate Federal Register Notice Liaison Officer, Department of Defense. [FR Doc. 01–21634 Filed 8–27–01; 8:45 am] BILLING CODE 5001–08–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1010-F]

RIN 0938-AK66

Medicare Program; Replacement of Reasonable Charge Methodology by Fee Schedules for Parenteral and Enteral Nutrients, Equipment, and Supplies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS. ACTION: Final rule.

SUMMARY: This final rule implements fee schedules for payment of parenteral and enteral nutrition (PEN) items and services furnished under the prosthetic device benefit, defined in section 1861(s)(8) of the Social Security Act. The authority for establishing these fee schedules is provided by the Balanced Budget Act of 1997, which amended the Social Security Act at section 1842(s). Section 1842(s) of the Social Security Act specifies that statewide or other areawide fee schedules may be implemented for the following items and services still subject to the reasonable charge payment methodology: medical supplies; home dialysis supplies and equipment; therapeutic shoes; parenteral and enteral nutrients, equipment, and supplies; electromyogram devices; salivation devices; blood products; and transfusion medicine. This final rule describes changes made to the proposed fee schedule payment methodology for these items and services and provides that the fee schedules for PEN items and services are effective for all covered items and services furnished on or after January 1, 2002. Fee schedules will not be implemented for electromyogram devices and salivation devices at this time since these items are not covered by Medicare. In addition, fee schedules will not be implemented for medical supplies, home dialysis supplies and equipment, therapeutic shoes, blood products, and transfusion medicine at this time since the data required to

establish these fee schedules are inadequate.

DATES: These final regulations are effective January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 786–4499.

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I. Background

The provisions of sections 1833 and 1842 of the Social Security Act (the Act) set forth the general payment authority for most physician and other medical and health services furnished under Part B of the Medicare program. Section 1842(s) of the Act, added by section 4315 of the Balanced Budget Act of 1997 (BBA), (Pub. L. 105–33) provides authority for implementing statewide or other areawide fee schedules to be used for payment of the following items and services that are paid on a reasonable charge basis when covered:

• Medical supplies.

- Home dialysis supplies and equipment.
 - Therapeutic shoes.

• Parenteral and enteral nutrients, equipment, and supplies.

- Electromyogram devices.
- Salivation devices.
- Blood products.
- Transfusion medicine.

Section 1842(s)(1) of the Act provides that if fee schedules are established for any of the covered items and services listed above, the fee schedules are to be updated on an annual basis by the percentage increase in the consumer price index for all urban consumers (CPI–U) for the 12-month period ending with June of the preceding year. The fee schedules for PEN items and services, however, may not be updated before the year 2003. Finally, section 4315(d) of the BBA requires that the first year's fee schedules be set so that they are budgetneutral (that is, total payments for the initial year of the fee schedules for particular services must be approximately equal to the estimated payments that would have been made for those services under the reasonable charge payment methodology).

We published a proposed rule on July 27, 1999 (64 FR 40534) that described the methods proposed for computing fee schedules for the covered items and services listed above. The proposed rule stated that the fee schedules would apply to items and services furnished on or after January 1, 1999 and would be calculated using base reasonable charges updated by an update factor as mandated by the BBA. The proposed rule provided that statewide fee schedule amounts would be calculated for all items and services except PEN items and services, which would have nationwide fee schedule amounts. In accordance with section 4551(b) of the BBA, the nationwide fee schedule amounts for PEN items and services would be equal to the lesser of: (1) The 1995 reasonable charges; or (2) the 1998 reasonable charges, increased by the inflation adjustment factor that would have otherwise been used in calculating the 1999 inflation-indexed charges (in effect, the 1999 reasonable charges). The proposed rule also called for national fee schedule ceiling and floor limits for medical supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine furnished within the continental United States

Medicare currently does not cover electromyogram devices or salivation devices; therefore, we do not plan to establish fee schedules for these items at this time. Also, fee schedules will not be established at this time for medical supplies, home dialysis supplies and equipment, therapeutic shoes, blood products, and transfusion medicine. The data needed to establish these fee schedule amounts so that they meet the budget-neutrality requirement of section 4315(d) of the BBA are currently not available. We are establishing fee schedules only for PEN items and services in this final rule. In the event that it becomes possible to establish budget-neutral fee schedules in the future for the other items and services addressed in the proposed rule, we will establish these fee schedules in one or more separate final rules.

II. Summary of Public Comments and Responses

We received comments from five groups representing the industry, two individual suppliers, and one member of the Congress who wrote on behalf of a constituent hospital. We have summarized the comments pertaining to the fee schedules for PEN items and services and present them below along with our responses. We have not included the comments pertaining to those items and services for which we have decided not to implement fee schedules at this time.

Effective Date for Implementation of Fee Schedules

Comment: Several commenters suggested that the fee schedules should not be implemented retroactively based on an effective date of January 1, 1999. One commenter suggested that the fee schedules be implemented no sooner than 60 days after the date of the final rule.

Response: We did not intend to apply this rule retroactively, and are changing the effective date from that proposed in the NPRM to January 1, 2002 to take into account the publication date of the final rule. The fee schedules for PEN items and services will apply to items and services furnished on or after January 1, 2002.

List of Health Care Financing Common Procedure Coding System (HCPCS) Codes Subject to the Fee Schedules

Comment: One commenter asked which HCPCS codes would be subject to the fee schedules.

Response: The list of HCPCS codes subject to the fee schedules established by this final rule will change as codes are added to and deleted from the HCPCS. The following is the list of HCPCS codes currently subject to the fee schedules established by this final rule:

PEN ITEMS AND SERVICES

B4034	Enteral Feeding Supply Kit;
B4035	Syringe, per day Enteral Feeding Supply Kit; Pump Fed, per day
B4036	Enteral Feeding Supply Kit; Gravity Fed, per day
B4081	Nasogastric Tubing with Sty-
B4082	Nasogastric Tubing without Stylet
B4083	Stomach Tube—Levine Type
B4084	Gastrostomy/Jejunostomy Tubing
B4085	Gastrostomy Tube, Silicone with sliding ring, each

PEN ITEMS AND SERVICES—Continued

I; semi-synthetic intact Protein/Protein Isolates, administered through an enteral feeding tube, 100 calories = 1 unitB4151Enteral Formulae; category I; Natural Intact Protein/Pro- tein Isolates, administered through an enteral feeding tube, 100 calories = 1 unitB4152Enteral Formulae; Category II; Intact Protein/Protein Isolates (calorically dense), administered through an enteral feeding tube, 100 calories = 1 unitB4153Enteral Formulae; Category III; Hydrolized Protein/ Amino Acids, administered through an enteral feeding tube, 100 calories = 1 unitB4154Enteral Formulae; Category III; Hydrolized Protein/ Amino Acids, administered through an enteral feeding tube, 100 calories = 1 unitB4154Enteral Formulae; Category IV; Definde Formula for Special Metabolic Need, administered through an enteral feeding tube, 100 calories = 1 unitB4155Enteral Formulae; Category V; Modular Components, administered through an enteral feeding tube, 100 calories = 1 unitB4164Parenteral Nutrition Solution: Carbohydrates (Dextrose), 50% or less (500 ML = 1 unit)—HomemixB4168Parenteral Nutrition Solution; Amino Acid, 3.5%, (500 ML = 1 unit)—HomemixB4176Parenteral Nutrition Solution; Amino Acid, greater than 8.5% (500 ML = 1 unit)— HomemixB4180Parenteral Nutrition Solution; Amino Acid, greater than 8.5% (500 ML = 1 unit)— HomemixB4186Parenteral Nutrition Solution; Lipids, 10% with Adminis- tration Set (500 ML = 1 unit)B4186Parenteral Nutrition Solution; Lipids, 20% with Adminis- tration Set (500 ML = 1 unit) </th <th></th> <th></th>		
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II; Intact Protein/Protein Isolates (calorically dense), administered through an enteral feeding 		through an enteral feeding
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IV: Definde Formula for Special Metabolic Need, administered through an enteral feeding tube, 100 	B4154	through an enteral feeding tube, 100 calories = 1 unit
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V; Modular Components, administered through an enteral feeding tube, 100 calories = 1 unitB4156Enteral Formulae; Category VI; Standardized Nutrients, administered through an enteral feeding tube, 100 calories = 1 unitB4164Enteral Formulae; Category VI; Standardized Nutrients, administered through an enteral feeding tube, 100 calories = 1 unitB4164Parenteral Nutrition Solution: Carbohydrates (Dextrose), 50% or less (500 ML = 1 unit)—HomemixB4168Parenteral Nutrition Solution; Amino Acid, 3.5%, (500 ML = 1 unit)—HomemixB4176Parenteral Nutrition Solution; Amino Acid, 7% through 8.5%, (500 ML = 1 unit)— HomemixB4178Parenteral Nutrition Solution; Carbohydrates (Dextrose), greater than 8.5% (500 ML = 1 unit)— HomemixB4180Parenteral Nutrition Solution; Carbohydrates (Dextrose), greater than 50% (500 ML = 1 unit)—HomemixB4184Parenteral Nutrition Solution; Lipids, 10% with Adminis- tration Set (500 ML = 1 unit)B4186Parenteral Nutrition Solution, Lipids, 20% with Adminis- tration Set (500 ML = 1 unit)B4189Parenteral Nutrition Solution, Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Ele- ments, and Vitamins, in- cluding preparation, any strength, 10 to 51 grams	D <i>4155</i>	enteral feeding tube, 100 calories = 1 unit
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B4164Parenteral Nutrition Solution: Carbohydrates (Dextrose), 50% or less (500 ML = 1 unit)—HomemixB4168Parenteral Nutrition Solution; 		administered through an enteral feeding tube, 100
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ML = 1 unit)—HomemixB4176Parenteral Nutrition Solution; Amino Acid, 7% through 8.5%, (500 ML = 1 unit)— HomemixB4178Parenteral Nutrition Solution; 	B4168	unit)—Homemix Parenteral Nutrition Solution:
8.5%, (500 ML = 1 unit)— HomemixB4178B4178Parenteral Nutrition Solution; Amino Acid, greater than 8.5% (500 ML = 1 unit)— 	B4176	ML = 1 unit)—Homemix Parenteral Nutrition Solution; Amino Acid, 7% through
Amino Acid, greater than 8.5% (500 ML = 1 unit)— HomemixB4180Parenteral Nutrition Solution; Carbohydrates (Dextrose), greater than 50% (500 ML = 1 unit)—HomemixB4184Parenteral Nutrition Solution; Lipids, 10% with Adminis- 	B4178	8.5%, (500 ML = 1 unit)— Homemix
Carbohydrates (Dextrose), greater than 50% (500 ML = 1 unit)—HomemixB4184Parenteral Nutrition Solution; Lipids, 10% with Adminis- 		Amino Acid, greater than 8.5% (500 ML = 1 unit)—
 B4184 B4184 Parenteral Nutrition Solution; Lipids, 10% with Adminis- tration Set (500 ML = 1 unit) Parenteral Nutrition Solution, Lipids, 20% with Adminis- tration Set (500 ML = 1 unit) B4189 Parenteral Nutrition Solution; Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Ele- ments, and Vitamins, in- cluding preparation, any strength, 10 to 51 grams 	B4180	Carbohydrates (Dextrose),
B4186tration Set (500 ML = 1 unit)B4186Parenteral Nutrition Solution, Lipids, 20% with Adminis- tration Set (500 ML = 1 unit)B4189Parenteral Nutrition Solution; Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Ele- ments, and Vitamins, in- cluding preparation, any strength, 10 to 51 grams	B4184	Parenteral Nutrition Solution;
Lipids, 20% with Adminis- tration Set (500 ML = 1 unit) Parenteral Nutrition Solution; Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Ele- ments, and Vitamins, in- cluding preparation, any strength, 10 to 51 grams	B4186	tration Set (500 ML = 1 unit)
B4189 Parenteral Nutrition Solution; Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Ele- ments, and Vitamins, in- cluding preparation, any strength, 10 to 51 grams		Lipids, 20% with Adminis- tration Set (500 ML = 1
Electrolytes, Trace Ele- ments, and Vitamins, in- cluding preparation, any strength, 10 to 51 grams	B4189	Parenteral Nutrition Solution; Compounded Amino Acid
strength, 10 to 51 grams		Electrolytes, Trace Ele- ments, and Vitamins, in-
		strength, 10 to 51 grams

PEN ITEMS AND SERVICES—Continued PEN items and services is 100 percent

		complete.
B4193	Parenteral Nutrition Solution;	Payment for Professional Set
	Compounded Amino Acid and Carbohydrates with	Associated With Furnishing
	Electrolytes, Trace Ele-	and Services
	ments, and Vitamins, in-	
	cluding preparation, any	<i>Comment:</i> Several comme
	strength, 52 to 73 grams	that we ignored the recomme
	of protein—Premix	the Congress that appeared i
B4197	Parenteral Nutrition Solution;	conference agreement on the
	Compounded Amino Acid	"* * * examine carefully th
	and Carbohydrates with	appropriateness of including
	Electrolytes, Trace Ele-	professional services * * *
	ments and Vitamins, in-	establishing the fee schedule
	cluding preparation, any	for PEN items and services.
	strength, 74 to 100 grams	<i>Response:</i> The Medicare p
	of protein—Premix	supplier who furnishes PEN
B4199	Parenteral Nutrition Solution;	equipment, and supplies to a
	Compounded Amino Acid	beneficiary includes paymer
	and Carbohydrates with	providing all services that ar
	Electrolytes, Trace Ele-	necessary to furnish the PEN
	ments and Vitamins, in-	
	cluding preparation, any	equipment, and supplies. Th
	strength, over 100 grams	payment for these services w
B4216	of protein—Premix Parenteral Nutrition; Addi-	predicated on the assumptio
D4210	tives (Vitamins, Trace Ele-	suppliers included in their c
	ments, Heparin, Electro-	medically necessary services
	lytes) Homemix per day	related to furnishing PEN nu
B4220	Parenteral Nutrition Supply	equipment, and supplies. Pa
	Kit; Premix, per day	services of a physician that a
B4222	Parenteral Nutrition Supply	to furnishing PEN, such as th
	Kit; Home Mix, per day	evaluation of the patient lead
B4224	Parenteral Nutrition Adminis-	prescription for PEN, are pai
	tration Kit, per day	separately under the Medica
B5000	Parenteral Nutrition Solution:	schedule for physicians' serv
	Compounded Amino Acid	However, the reasonable cha
	and Carbohydrates with	PEN items and services inclu
	Electrolytes, Trace Ele- ments, and Vitamins, in-	payment for services such as
	cluding preparation, any	supplier's assessment of the
	strength, Renal—Amirosyn	patient education, and gener
	RF, Nephramine,	provided by registered nurse
	Renamine—Premix	dispensing of nutrition supp
B5100	Parenteral Nutrition Solution:	licensed pharmacists that are
	Compounded Amino Acid	overall services furnished by
	and Carbohydrates with	supplier. Therefore, paymen
	Electrolytes, Trace Ele-	medically necessary services
	ments, and Vitamins, in-	associated with providing PI
	cluding preparation, any	nutrients, equipment, and su
	strength, Hepatic-	always been included in the
	Freamine HBC,	amounts developed under th
DOOOO	Hepatamine—Premix	reasonable charge payment
B9000	Enteral Nutrition Infusion Pump—without alarm	methodology, a methodology
B9002	Enteral Nutrition Infusion	suppliers' charges to calcula
D9002	Pump—with alarm	amounts. Because the fee scl
B9004	Parenteral Nutrition Infusion	
	Pump, portable	amounts for PEN items and s
B9006	Parenteral Nutrition Infusion	established by this final rule
	Pump, stationary	on the payment amounts tha
E0776XA	IV pole	developed under the reasona
	• ·	methodology, payment for a
		· · · · · · · · · · · · · · · · · · ·

Calculating Fee Schedule Amounts for Items and Services Where Reasonable Charge Data Is Unavailable

Comment: One commenter questioned how fee schedule amounts were going to be established for items and services for which reasonable charge data were unavailable during the data base period.

Response: The compilation of aggregate reasonable charge data for

ervices PEN Items

enters stated endation of in the e BBA to ıe g the costs of when e amounts

payment to a nutrients, a Medicare nt for re medicallv N nutrients, he Medicare was on that charges all s directly utrients, ayment for are related he initial ding to the id for are fee vices. arges for uded s the patient, ral care es, and olies by re part of the y the nt for all s directly EN upplies has e payment he y that uses ate payment hedule services e are based at were able charge inv necessary professional services provided by a supplier as part of furnishing PEN nutrients, equipment, and supplies to Medicare beneficiaries is included in the fee schedule amounts.

Moreover, it is important to note that the statute requires that the fee schedule amounts established by this final rule must be budget-neutral. Additional payment for professional services provided by suppliers furnishing PEN

nutrients, equipment, and supplies, would duplicate payment already included in the fee schedule rate and payments for all other PEN items and services would have to be reduced to maintain budget-neutrality. The total payment for PEN items and services would therefore remain the same.

Lump Sum Payment for PEN Items and Services

Comment: One commenter requested clarification regarding the provision in the proposed rule that payment for PEN items and services is to be made on a lump sum basis.

Response: The term "lump sum" generally refers to a one-time payment for the purchase of an item. Since payment for certain PEN items and services is made on a rental basis rather than a purchase basis, the use of the term "lump sum" in relation to payment for these rental PEN items is erroneous. Therefore, we have revised the rule to reflect that the term "lump sum" only applies to purchase transactions.

III. Provisions of the Final Regulations

The provisions of this final rule are the same as the provisions of the July 27, 1999, proposed rule except as noted below. The following changes have been made:

• Fee schedules will only be implemented for PEN items and services. Fee schedules will not be implemented at this time for electromyogram devices, salivation devices, medical supplies, home dialysis supplies and equipment, therapeutic shoes, blood products, and transfusion medicine.

• The initial year that the fee schedules will be in effect will be calendar year 2002 rather than calendar vear 1999.

• For PEN items and services, the fee schedule amounts will be based on the reasonable charges that would have been used in determining payment for these items and services in 2002.

• The section regarding payment for PEN items and services has been revised to reflect that payment for these items and services will be on either a rental basis for the equipment or in a lump sum amount for the purchase of the nutrient or supply.

The 2002 fee schedule amounts for all HCPCS codes for PEN items and services are listed below. Section 4551(b) of the BBA specifies that the reasonable charges for PEN items and services for 2002 may not exceed the reasonable charges for these items and services from 1995. Therefore, the fee schedule amounts for PEN items and services, other than codes B4176 and

B4222, are based on the reasonable charges for the items or services during 1995. We have determined that the reasonable charges for codes B4176 and B4222 for 2002 will be less than the reasonable charges from 1995. Therefore, the fee schedule amounts for codes B4176 and B4222 will be based on the amounts that would have been used in calculating the reasonable charges for 2002. A modifier (MOD), if applicable, identifies the service as either: purchase of new equipment (NU); purchase of used equipment (UE); or rental of equipment (RR).

2002 FEE SCHEDULE—PEN ITEMS AND SERVICES

HCPCS/MOD	Fee
B4034	\$5.60
B4035	10.67
B4036	7.31
B4081	19.78
B4082	14.73
B4083	2.25
B4084	16.52
D 1005	37.48
B4085 B4150	0.61
DALEA	1.43
B4151 B4152	0.51
B4152	1.74
B4153	1.12
B4154 B4155	0.87
	1.24
B4156 B4164	
-	15.08
B4168 B4176	40.99
B4176 B4178	51.04
D 4400	21.61
B4180 B4184	70.86
B4184 B4186	94.48
B4180 B4189	157.66
B4109 B4193	203.73
B4197	248.02
B4197	248.02
B4199 B4216	6.85
B4220	7.10
B4222	8.44
B4224	22.19
B5000	10.54
B5100	4.12
B9000NU	1,121.97
B9000RR	103.10
B9000UE	841.47
B9002NU	1,121.97
B9002RR	108.66
B9002UE	841.47
B90020E B9004NU	2,238.01
B9004RR	354.30
	1,678.51
	2,238.01
	2,238.01
B9006RR B9006UE	1.678.51
	93.30
E0776NU	93.30
	23.62
E0776UE	29.15

IV. Collection of Information Requirements

This document does not impose information collection and

recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et. seq.*)

V. Regulatory Impact Statement

We have examined the impact of this final rule as required by Executive Order (EO) 12866, the Unfunded Mandates Reform Act (UMRA) (Pub. L. 104-4), the Regulatory Flexibility Act (RFA) of 1995 (Pub. L. 96-354), and the Federalism Executive Order (EO) 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more annually). This rule will not result in a change in expenditures of \$100 million or more annually, and is therefore not a major rule as defined in Title 5. United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of \$5 million to \$25 million annually. Individuals and states are not included in the definition of a small entity. Based on data from the Small Business Administration (SBA), we estimate that 98 percent of suppliers of the items and services affected by this rule would be defined as small entities for purposes of the RFA. Due to the fact that the statewide fee schedule amounts will be calculated using the average of the payment amounts made in each State under the reasonable charge payment methodology, we expect that the overall impact of this rule on small businesses will be minimal.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

In the proposed rule we certified that this rule would not have a significant impact on a substantial number of small entities and on small rural hospitals. Since we did not receive any comment on our initial regulatory impact statements, we are conforming our initial determination and certifying that this rule will not have a significant impact on a substantial number of small entities including small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule would not have an effect on the governments mentioned, and private sector costs would be less than the \$110 million threshold.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does not significantly affect the rights, roles, and responsibilities of State or local governments.

42 CFR part 414 is amended as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

2. A new subpart is added to read as follows:

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

§414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

§414.102 General payment rules.

(a) General rule. For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of——

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with \$\$ 414.104.

(b) Payment classification. (1) HCFA or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in § 414.104.

(2) HCFA designates the specific items and services in each category through program instructions.

(c) Updating the fee schedule amounts. For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year.

§414.104 PEN Items and Services.

(a) Payment Rules. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) Fee schedule amount. The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

(Catalog of Federal Domestic Assistance Programs No. 93.774, Medicare-

Supplementary Medical Insurance Program) Dated: August 1, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 8, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–21657 Filed 8–27–01; 8:45 am] BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[CS Docket No. 98-132; FCC 99-12]

1998 Biennial Review—Multichannel Video and Cable Television Service

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: This document announces the effective date of the rules published on September 5, 2000. Those rules amended the Commission's cable television rules pertaining to the public file, notice and recordkeeping

requirements. These rules contained information collection requirements that required the approval of the Office of Management and Budget ("OMB") before they could become effective. These rule sections have been approved by OMB and become effective on August 28, 2001.

DATES: Sections 76.1622, 76.1713, and 76.1800 published at 65 FR 53610 (September 5, 2000) are effective on August 28, 2001.

FOR FURTHER INFORMATION CONTACT:

Sonia Greenaway of the Consumer Protection and Competition Division, Cable Services Bureau at (202) 418–7200 TTY (202) 418–7172.

SUPPLEMENTARY INFORMATION: A summary of the public file, notice, and

recordkeeping requirements set forth in Part 76 of the Commission's cable television rules in CS Docket No. 98-132, 1998 Biennial Regulatory Review-Streamlining of Cable Television Services Part 76 Public File and Notice Requirements, Report and Order (FCC 99-12, 14 FCC Rcd 4653 (1999)) was published in the Federal Register at 65 FR 53610 (Sept. 5, 2000). The rules revised and streamlined the public file and notice requirements, and reduced the regulatory burden faced by cable operators. Sections 76.1622, 76.1713, and 76.1800 contained information collection requirements that required approval from OMB before they could become effective. OMB approved the information collection requirements on June 7, 2001. See OMB No. 3060–0981. Accordingly, §§ 76.1622, 76.1713, and 76.1800 become effective on August 28, 2001. This document constitutes publication of the effective date of those sections.

List of Subjects in 47 CFR Part 76

Multichannel video and cable television service.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–21626 Filed 8–27–01; 8:45 am] BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 107, 171, 172, 173, 175, 176, 177, 178, 179, 180

[Docket No. RSPA-01-10374 (HM-189S)]

RIN 2137-AD60

Hazardous Materials Regulations: Editorial Corrections and Clarifications

AGENCY: Research and Special Programs Administration (RSPA), DOT. **ACTION:** Final rule.

SUMMARY: This final rule corrects editorial errors, makes minor regulatory changes, and, in response to requests for clarification, improves the clarity of certain provisions in the Hazardous Materials Regulations (HMR). The intended effect of this rule is to enhance the accuracy and reduce misunderstandings of the HMR. The amendments contained in this rule are minor editorial changes and do not impose new requirements.

EFFECTIVE DATE: October 1, 2001.

FOR FURTHER INFORMATION CONTACT: Michael G. Stevens, Office of Hazardous Materials Standards, (202) 366–8553, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001. SUPPLEMENTARY INFORMATION:

SUPPLEMENTART INFORMATION

Background

RSPA (we) annually reviews the HMR to identify and correct errors. Inaccuracies corrected in this final rule include typographical and printing errors, incorrect references to other rules and regulations in the CFR, inconsistent use of terminology, and misstatements of certain regulatory requirements. In response to inquiries RSPA received concerning the clarity of particular requirements specified in the HMR, certain other changes are made to reduce uncertainties.

Because these amendments do not impose new requirements, notice and public procedure are unnecessary. In addition, making these amendments effective without the customary 30-day delay following publication will allow the changes to appear in the next revision of 49 CFR.

The following is a section-by-section summary of the amendments made under this final rule. It does not discuss all minor editorial corrections (*e.g.*, typographical, capitalization and punctuation errors), changes to legal authority citations and certain other